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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,310	09/29/2003	Klaus Heilmann	2565/112	5354

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EXAMINER	
MENON, KRISHNAN S	

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/675,310	HEILMANN ET AL.	
	Examiner	Art Unit	
	Krishnan S. Menon	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-64,67-78,81-92,94-105,107-117 and 119-133* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55-64,67-78,81-92,94-105,107-117 and 119-133* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 55-64, 67-78, 81-92, 94-105, 107-117 and 119-133 are pending as amended 6/6/06.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 127-133 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,641,731. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent recite all the same limitations of the instant claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 55-64, 67, 69,70,71,76-78, 81, 83-92, 94, 95, 97-99,101,104, 105, 107, 108,121 and 124 are rejected under 35 U.S.C. 102(b) as being anticipated by Hankammer (US 4,885,089).

Claim 55, 83: Hankammer teaches an end cap for a filter (title, figures 1,3) comprising a generally axial inlet flow path (9), curved members extending in the axial direction away from an interior surface of the end cap (4, figure 5) defining a flow radial direction for a fluid exiting the end cap as claimed. Curved member and the end cap are single structural components as claimed.

Claims 69,97, 121, 124: Hankammer also teaches a filter in combination and a method of filtering by passing a fluid through a filter having such an end cap - (see column 2 lines 5-35). Curved member and the end cap are single structural components as claimed.

Claims 56-58, 84-86: the end cap can be attached to a dialyzer; 'blood inlet channel' is intended use. A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the

structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)

Claims 59-61, 87-89, 101: flow direction as claimed – see figures and column 2 lines 5-35)

Claims 62-64, 67 and 76-78, 81, 90-92, 94, 95, 104,105, 107,108: the members are integrally formed, extends to the perimeter, arranged circumferentially around the channel, curved, radially symmetrical, equidistant to one-another, and the flow directions are as claimed – see figures.

Claims 70,71,98,99: the channel is an inlet channel – column 2 lines 5-35. dialyzer and blood inlet channel are intended use – Ex parte Masham.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 55-64, 67, 69-78, 81, 83-92, 94,95, 97-105, 107, 108, 110-117, 119 and 121-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanno et al (US 4,201,673) in view of Hankammer'089..

Kanno teaches a dialyzer (figure 2 and abstract) comprising an inlet end cap, and plurality of hollow fibers as claimed with the inlet channel being blood inlet; and a method of filtering blood.

The teaching of Kanno differs form the claims in that Kanno does not teach the curved members extending from an interior surface that is adjacent to the channel of the end cap. Hankammer teaches an end cap for filter cartridges having an axial inlet and curved members integrally formed which are symmetrical and equidistant to one-another and render the flow from axial to radial as claimed. It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Hankammer in the teaching of Kanno for improved distribution of blood without channeling as taught by Hankammer (see column 2 lines 5-35). One would use the teaching of Hankammer in the teaching of Kanno because Kanno recognizes the need for proper distribution of blood without channeling and Hankammer teaches an improved structure for obtaining such distribution (Kanno column 3 line 45 – column 4 line 39).

3. Claims 55-64, 67-78, 81-92, 94-105, 107-117, 119-127 and 131-133 are rejected under 35 U.S.C. 103(a) as being unpatentable over German Patent No. 3435883 (hereinafter referred to as GP (883).

GP :883 teaches a dialyzer comprising a casing (12) containing hollow fibers and an end cap (24) attached to the casing (10) wherein the end cap (24) comprises a blood inlet channel (28) in axial direction relative to hollow fibers and curved members (50) arranged circumferentially and equidistant from each other to impart circular motion in a first direction (see figures 1-2). With regard to the first generally axial and second flow directions, the flow direction is axial at the inlet at 28, and then changes to radially outward through the curved members and then changes to radially inward under the

member 46 – see flow direction arrow in the figure 1. With regard to the curved members being extending in the first direction away from an interior surface, the vanes extend form an interior surfaces (46 and 54) of the end cap in the axial direction. Please note that the member (46) can also be in the shape of a cone with its apex oriented towards the aperture (28) (see English translation, page 13, bottom paragraph). This structure particularly reads on to the claim language 'curved member extending from an interior surface of the end cap that is adjacent to the channel in a direction same as the first generally axial direction'. Also see page 14, 3rd paragraph of the English translation, in which the elements (50) are also described as serving as spacers that prevent the plate (46) from resting against the end cap, which means the elements (50) can be in physical contact with the surface (54) of the end cap as well, which would make the elements (50) as extending also from the surface (54).

The reference differs from the claims in the recitation of the curved member and the end cap being a single structural component. However this would be only making the curved member part of the end cap instead of being separate from the end cap as in the reference, which is not patentable: "...the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice" (*In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965)). Applicant's argument, that it is patentable because the flat disc 46 was eliminated but its function retained, is not persuasive because the circular flow is provided by the ribs, not the plate or cone (46); the ribs are retained in the same physical location to provide the

same function. Moreover, the claim language being open-ended does not eliminate the disc or cone (46).

With regard to claims 121-126, the reference teaches the method of filtering by passing a fluid through the filter device; the filter device being a dialyzer, and the fluid being blood. See page 17 of the English translation.

Claims 68,82,96,109,120: These claims recite the sub-combination end cap or the combination filter device, which are taught by the reference – see figures. Channel from exterior to interior – 26. Flow path in the first direction – 28. A member located inside, and extending from the interior chamber – 46, which is straight or conical (see English translation, last paragraph in page 13) and provides a flow direction different from the first direction to the fluid. End cap includes two members – 54 and 46 – respective portions of which are spaced equidistantly, and the spacing between which decrease in the flow direction. The vanes 50 are also configured to impart a circular motion to the fluid.

Claims 127, 131-132: radial inlet to the end cap would be obvious to one of ordinary skill in the art - only a change of shape from the axial inlet provided in the reference: In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.). Changes of size, shape, etc without special functional significance are not patentable. Research Corp. v. Nasco Industries, Inc., 501 F2d 358; 182 USPQ 449 (CA

7), cert. denied 184 USPQ 193; 43 USLW 3359 (1974). The axial channel will require a curvature of a quarter turn (or a 90 deg. bend) to connect to a radial inlet.

Claim 133: connection to the interior to the housing and exterior to the hollow fibers – see 18, which is on the shell of the housing in the reference instead of the end cap as claimed. However, the location of this connection on the end cap is only an obvious equivalent, unless applicant can show otherwise, because this connection performs the same function. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982).

Response to Arguments

Applicant's arguments filed 6/6/06 have been fully considered but they are not persuasive.

Arguments regarding the Heilmann reference has been addressed in the rejection.

With respect to the Hankammer reference: the limitation, "channel that defines a fluid flow path in the generally axial direction" [emphasis in original], is not a patentable limitation since the channel of Hankammer is capable of having a fluid flow in the axial direction. In addition, air is a fluid; air escaping the vent cap is in the axial direction. The argument that it does not function as a fluid flow path is not convincing because air is a fluid, and functional language does not make the claim patentable if the prior art is so capable.

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)

As explained in *In re Schreiber* 44 USPQ2d 1429 (CA FC 1997): "A patent applicant is free to recite features of an apparatus structurally or functionally. [ ] Yet, choosing to define an element functionally, *i.e.,* by what it does, carries with it a risk. As our predecessor court stated in *Swinehart,* 439 F.2d at 213, 169 USPQ at 228: where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied upon".

"where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact,

be an inherent characteristic of the prior art, it possesses the authority to require applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied upon" *In re Swinehart* 169 USPQ 226, 229 (CCPA 1971).

With respect to the argument that the combination of Kanno and Hankammer does not render the present claims obvious: Column 2 lines 23-31 of Hankammer teaches the advantages of having the vanes to guide the water to uniformly penetrate the screen over its entire cross-section, which affords a uniform distribution of water instead of it falling vertically through the filtering material. One of ordinary skill in the art would be motivated to use this teaching of the Kanno reference to obtain the distribution as required in Kanno reference, column 3 line 65 – column 4 line 2.

Applicant's arguments about the Kanno reference being rendered inoperable by this combination are all misplaced. Use of the vanes taught by the Hankammer reference in the Kanno inlet would not make the Kanno reference inoperable. Combining the references does not mean that they are being bodily incorporated in to each other.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Krishnan S Menon 6/13/06
Examiner
Art Unit 1723